



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,194	12/01/2003	John Fitzgerald Kokai-Kun	7787.0061-00	1338

959 7590 08/03/2007
LAHIVE & COCKFIELD, LLP
ONE POST OFFICE SQUARE
BOSTON, MA 02109-2127

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
----------	--------------

1645

MAIL DATE	DELIVERY MODE
-----------	---------------

08/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/724,194

Applicant(s)

KOKAI-KUN ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,21-25,28 and 39-58 is/are pending in the application.
- 4a) Of the above claim(s) 39-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,21-25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 18, 21-25, 28, 39-58 are pending.

Claim 18 has have been amended.

Claims 18, 21-25 and 28 are under consideration.

Claims 39-58 remain withdrawn from consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

1. Claims 18-19 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorland et al (1998) in light of the amendment of the independent claim to limit the invention to monoclonal antibodies.
2. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by White et al (1983), in light of the amendment of the independent claim to limit the invention to monoclonal antibodies.
3. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Godin et al (1980), in light of the amendment of the independent claim to limit the invention to monoclonal antibodies.
4. The rejection of claims 18, 21-25, 28 under 35 U.S.C. 112, first paragraph is herein withdrawn in light of Applicant's amendment of claim 21 to remove the phrase "the Mabs have non identical amino acid sequences" and traversal.

Objections/Rejections Maintained/ Response to Arguments

5. Applicant's arguments filed May 7, 2007 have been fully considered but they are not persuasive.
6. ***Claim Rejections - 35 USC § 103*** Claims 18, 21-25 and 28 under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (US Pat. 6,939,543, filing date June 2001) in view of Patti (US Pat. 6,703,025, filing date August 31, 1999) is traversed on the grounds that:
7. Fischer et al fail to teach monoclonal antibodies that bind specifically to ribitol phosphate wall teichoic acid of *S. aureus*.

8. It is the position of the examiner that Fischer et al describe combination compositions of antibodies for antibody therapy (see col. 11, lines 16-18 and col. 11, lines 32-34), and obtain the combination composition of antibodies by immunization with mixtures of antigens, to include both types of teichoic acid antigens (see col. 11, lines 41-50).

9. It has long been held that a reference must be evaluated in its entirety, not on the basis of its preferred embodiments or working examples. *In re Mills*, 470 F.2d 649, 651, 176 (USPQ 198 (CCPA 1972)). While a focus of Fischer et al is directed to the production of anti-glycerol teichoic acid antibodies, the reference also describes the production of additional antibodies to additional antigens present in *Staphylococcus aureus* lipoteichoic acid. Fischer et al specifically teach the teichoic acids of *Staphylococcus aureus* to comprise ribitol phosphate and glycerol phosphate in the *S.aureus*' teichoic acid (see col. 5, lines 32-35), and Fischer et al states their antibodies are directed to "LTA exposed on the surface of the cell wall of Gram positive bacteria (paragraph 2)" and goes on to state: "Teichoic acids are polymers of either glycerol phosphate or ribitol phosphate with various sugars (paragraph 3) ". Therefore Fischer teaches and suggests combination compositions of antibodies directed to ribitol phosphate and glycerol phosphate antigens.

10. Applicant asserts that Patti et al fail to teach and suggest anti-teichoic antibodies that could be protective and do not teach monoclonal antibodies to ribitol teichoic acid.

11. It is the position of the examiner that Fischer et al teach to production of polyclonal, monoclonal, chimeric, human and humanized antibodies to *S. aureus* teichoic acids and suggests antibodies to glycerol and ribitol phosphate antigens. Patti et al was cited to show that ribitol

11. phosphate is immunogenic, and induces antibodies, wherein polyclonal antibodies to ribitol phosphate have been made. Patti et al teach the production of antibodies to glycerol or ribitol phosphate in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52) associated with staphylococcal antigens (abstract) to increase the opsonization and phagocytosis of *S. aureus* (see col. 22, lines 30-35 and 48-52).
12. Fischer et al teach the formulation of anti-LTA antibodies into pharmaceutical compositions that comprise a “therapeutically effective amount of a pharmaceutical composition comprising the anti-LTA immunoglobulin (whether polyclonal or monoclonal or chimeric, including fragments, regions and derivative thereof) and a pharmaceutically acceptable carrier.”
13. Fischer et al in view of Patti et al provide guidance, teaching, suggestion and motivation to make monoclonal, chimeric, humanized and human antibodies to ribitol teichoic acid, a wall component of known human pathogenic strains of *Staphylococcus aureus* because Fischer et al teach antibodies directed to lipoteichoic acids “can block the binding of Gram positive bacteria to epithelial cells, such as human epithelial cells (Fischer et al, first paragraph)” and Patti et al teach ribitol phosphate is immunogenic and induces antibodies directed to *S. aureus* LTA. It is obvious to make a monoclonal antibody to an antigen for which polyclonal antibodies have been made. In re Erlich, 1988. Fischer et al in view of Patti et al obviate the instantly claimed invention as now claimed.

Specification

14. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. see page 71, citation 27.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
July 30, 2007


MARK NAVARRO
PRIMARY EXAMINER